UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(609) 989-2040

CHAMBERS OF
TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
402 E. STATE STREET, RM 6052
TRENTON, NJ 08608

July 28, 2010

LETTER ORDER

Re: SPD Swiss Precision Diagnostics GmbH v Church & Dwight Co., Inc.
Civil Action No. 09-1802 (FLW)
Church & Dwight Co., Inc v SPD Swiss Precision Diagnostics GmbH
Civil Action No. 10-0276 (FLW)

Dear Counsel:

The Court has received and reviewed the parties' letter briefs regarding SPD Swiss Precision Diagnostics ("SPD") request that certain documents that Church & Dwight Co., Inc. ("C&D") designated as "Highly Confidential - Attorneys' Eyes Only" (AEO") be re-designated as "Confidential." C&D claims protection for its filings with the Food & Drug Administration ("FDA") under 21 C.F.R. § 20.61. In that section, the FDA defines

> (a) A trade secret may consist of any commercially valuable plan, formula, process or device that is used for the making, preparing, compounding, or processing of trade commodities . . . There must be a direct relationship between the trade secret and the productive process.
> (b) Commercial or financial information . . .is of a type customarily held in strict confidence or regarded as privileged . . .

The Court, having reviewed the documents, notes that some of the information contained in C&D's 510(k) application that has been designated AEO appears on the FDA website (www.fda.gov). For example, in the "510(k) Substantial Equivalence Determination Decision Summary" information can be found in documents with Bates Nos. CDSPD0000630, CDSPD0002193, CDSPD0000533 and CDSPD0000543 - 4. Many of the AEO designated pages are individual results that are summarized in the tables found on the FDA website. The Court also notes that under FDA regulations, once a class II device has been approved, data and information relating to safety and effectiveness shall be available for public disclosure unless it is a trade secret or commercial or financial information. (21 C.F.R. § 807.95(e)). The Court also notes that while an

application is pending before the FDA, the agency treats the existence of the application as confidential commercial information and once the application has been approved, confidentiality cannot be granted beyond 30 days after the approval, calling into question the commercial significance of correspondence between FDA and an applicant during the pendency of an application once an application has been approved. The Court instructs C&D to re-designate as Confidential and not AEO within five days of this order the following categories of documents:

1. Sections of C&D's 510(k) Premarket Notification that appear on the FDA website in summary tables or as statistical analysis as well as the individual records on which that the summary is based;
2. Sections of C&Ds 510(k) Premarket Notification data and information relating to safety and effectiveness of approved marketed devices; and
3. Correspondence with the FDA that is of a routine nature or does not disclose a trade secret, or commercial or financial information as defined in 21 C.F.R. § 20.61(a)-(b).

The following categories of documents remain designated as AEO at this time:

1. Any correspondence or document that discloses a trade secret, commercial or financial information as defined in 21 C.F.R. § 20.61 (a)-(b);
2. Any documents or correspondence that contain information or data that is part of or relates to any pending applications, supplements to current 510(k) Premarket Notification or concerning any device or product that is not currently approved for marketing.

IT IS SO ORDERED.

s/ Tonianne J. Bongiovanni
TONIANNE J. BONGIOVANNI
United States Magistrate Judge